

Notice of Allowability

Application No.

10/684,233

Examiner

Golam M M Shameem

Applicant(s)

BROWN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/09/03.
2. ☒ The allowed claim(s) is/are 1-10 and 13 (now 1-11).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Election/Restrictions

The Markush group set forth in the claims includes both independent and distinct inventions, and patentable distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentable distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentable distinct methods, also far too numerous to list individually. ***For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121***, wherein a Group is a set of patentable distinct inventions of a broad statutory category (e.g. compounds, methods of use, methods of making, etc.):

- I. Claims 1-10, 13 drawn to a compound and composition of formula (1) classified in classes 548, 514 and plethora of subclasses.
- II. Claims 11-12 drawn to a process for preparing a compound of formula (1) classified in class 548, and plethora of subclasses.
- III. Claims 14-17 drawn to a method of treating a disease classified in class 514, and plethora of subclasses.
- IV. Claims 18-19 drawn to intermediate compounds classified in class 548, and plethora of subclasses.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Group listed above are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level

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of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lahu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Inventions I-IV are related as product, process of making and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed could be used in a materially different process of using that product as demonstrated throughout the specification and in claims 14-17 for example, which are specifically directed to different methods of using the product. Therefore a separate search considerations are involved, which would impose a burden if unrestricted. Also the fields of search are not coextensive. Additionally, besides

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performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search.

The products of groups I-IV differ materially in structure and in element. The invention Group I-IV outlined above relates to a set of structurally diverse and dissimilar compounds, process of making and their method of uses, which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. In addition, because of the plethora of classes and subclasses in each of the Group, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

In the instant case, the different and distinct inventions are drawn to a single application, requiring different search strategies because of the different compounds, process of making (group II, reactive steps and conditions involved), methods of uses (group III) and intermediate compounds (group IV) and to search all the above groups in a single application would be an undue burden on the Examiner. Invention group III is distinct and independent from other Invention groups, because it is directed to different statutory class of invention and, the practice of Invention III, for example, would not result in the practice of the other invention. In addition, because of the plethora of classes and subclasses in each of the Group, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Where an election of any one of Groups I-IV is made, an election of a single compound is further required including an exact definition of each substitution on the base molecule, wherein a single member at each substituent group or moiety is selected. Upon the election of a single disclosed compound (e.g. Example, page number and structural depiction), a generic concept, inclusive of the elected compound, will be identified by the Examiner for examination along with the elected species. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound will be determined. A clear statement of the examined invention, defined by those class (es) and subclass (es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compound are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 applies with regard to double patenting covering divisional applications.)

Applicant is reminded that upon cancellation of claims to a nonelected invention, the inventions must be amended in compliance with 37 C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (subclasses), restriction for examination purpose as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Robert T Ronau on 5/17/04 to request an oral election to the above restriction requirement, and a provisional election was made with traverse to prosecute the invention of group I.

Status of Claims

Claims 1-19 are pending in the application.

Priority

This application claims benefit of 60/438,639, filed 01/08/2003, which claims benefit of foreign priority under 35 U.S.C. § 119(a)-(d) to EPO 02292513.5, filed 10/11/2002 and EPO 03290069.8, filed 01/10/2003 is acknowledged.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 10/09/03, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, (which includes claims 1-10 and 13) drawn to a compound and composition of formula (1) with traverse and the elected species as set forth in Example 1, on page 32, is acknowledged.

Claims 11-12 and 14-19 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Examiner's amendment

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Mr. Robert T. Ronau on June 16, 2004 and August 16, 2004 respectively.

The application has been amended as follows:

- a. Claims 11-12 and 14-19 have been canceled.
- b. In claim 1, line 12, page 89 and all other occurrences such as in claims 2-4 and 6-9, delete "and/or isomer" and insert with ----stereoisomer----.
- c. After the Title and before the first paragraph, please insert ----this application claims benefit of 60/438,639, filed 01/08/2003, which claims benefit of foreign priority under 35 U.S.C. § 119(a)-(d) to EPO 02292513.5, filed 10/11/2002 and EPO 03290069.8, filed 01/10/2003----.

Reasons for allowance

The following is an Examiner's statement of reasons for allowance:

Dow *et al* (EP 0822185) teach the compounds of the formula (I), which are beta-adrenergic receptor agonists having therapeutic activity such as antidiabetic and antiobesity

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agents. The instant compounds differ from the prior art by having a core indole ring, which are further substituted directly, or indirectly by different variables such as R_1 , R_2 , R_3 , R_4 - R_8 (attached to a benzene molecule through a nitrogen link) and n . The prior art compounds neither teach nor render obvious the instant claimed compounds and there is no suggestion or motivation to modify the compounds of other prior art to obtain the instant compounds. Therefore the instant claims are allowable over the prior art of record.

The reference cited on the PTO-892 is included only to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet

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e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'M M Shameem', with a stylized, overlapping initial 'M'.

Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1

August 17, 2004